



Robert Greene Steme  
Edward J. Kessler  
Jorge A. Goldstein  
David K.S. Cornwell  
Robert W. Esmond  
Tracy-Gene G. Durkin  
Michele A. Cimbala  
Michael B. Ray  
Robert E. Sokohl  
Eric K. Steffe  
Michael Q. Lee  
Steven R. Ludwig  
John M. Covert  
Linda E. Alcorn  
Robert C. Millonig  
Donald J. Featherstone  
Timothy J. Shea, Jr  
Michael V. Messinger

Judith U. Kim  
Patrick E. Garrett  
Jeffrey T. Helvey  
Heidi L. Kraus  
Eldora L. Ellison  
Thomas C. Fiala  
Donald R. Banowitz  
Peter A. Jackman  
Jeffrey S. Weaver  
Kendrick P. Patterson  
Vincent L. Capuano  
Brian J. Del Buono  
Virgil Lee Beaston  
Theodore A. Wood  
Elizabeth J. Haanes  
Joseph S. Ostroff  
Frank R. Cottingham  
Rae Lynn P. Guest

Daniel A. Klein  
Jason D. Eisenberg  
Michael D. Specht  
Tracy L. Muller  
Jon E. Wright  
LuAnne M. DeSantis  
Ann E. Summerfield  
Helene C. Carlson  
Cynthia M. Bouchez  
Timothy A. Doyle  
Gaby L. Longsworth  
Lori A. Gordon  
Nicole D. Dretar  
Ted J. Ebersole  
Laura A. Vogel  
Bryan S. Wade  
Aaron L. Schwartz  
Shannon A. Carroll\*

Wesley W. Jones\*  
Matthew E. Kelley\*  
Michelle K. Holoubek\*  
Marsha A. Rose\*  
**Registered Patent Agents\***  
Karen R. Markowicz  
Nancy J. Leith  
Matthew J. Dowd  
Katrina Yujian Pei Quach  
Bryan L. Skelton  
Robert A. Schwartzman  
Teresa A. Colella  
Victoria S. Rutherford  
Simon J. Elliott  
Julie A. Heider  
Mita Mukherjee  
Scott M. Woodhouse

Christopher J. Walsh  
Liliana Di Nola-Baron  
Peter A. Socarras  
Jeffrey Mills  
Danielle L. Letting  
**Of Counsel**  
Kenneth C. Bass III  
Marvin C. Guthrie  
  
\*Admitted only in Maryland  
\*Admitted only in Virginia  
\*Practice Limited to  
Federal Agencies

November 15, 2005

**WRITER'S DIRECT NUMBER:**  
(202) 772-8762

**INTERNET ADDRESS:**  
NLEITH@SKGF.COM

Commissioner for Patents  
PO Box 1450  
Alexandria, VA 22313-1450

**Art Unit: To Be Assigned**

**Attn: Mail Stop PCT**

Re: U.S. Utility Patent Application  
(U.S. National Phase of PCT/JP2004/005973; Int'l Filing Date: May 6, 2004)  
For: **Freeze-Dried Preparation Containing Methylcobalamin and Process  
For Producing Same**

Inventors: KATO *et al.*  
Our Ref: 1089.0590000/SRL/NJL

Sir:

Transmitted herewith for appropriate action are the following documents:

1. Information Disclosure Statement Filing Under 37 C.F.R. § 1.97(b);
2. Form PTO/SB/08A listing eight (8) documents (FP1-FP8);
3. Form PTO/SB/08B listing fourteen (14) documents (NPL1-NPL14);
4. Copies of cited documents FP1-FP8 and NPL1-NPL14; and
5. One (1) return postcard.

It is respectfully requested that the attached postcard be stamped with the date of filing of these documents, and that it be returned to our courier. In the event that extensions of time are necessary to prevent abandonment of this patent application, then such extensions of time are hereby petitioned.

Commissioner for Patents  
November 15, 2005  
Page 2

The U.S. Patent and Trademark Office is hereby authorized to charge any fee deficiency, or credit any overpayment, to our Deposit Account No. 19-0036.

Respectfully submitted,

STERNE, KESSLER, GOLDSTEIN & FOX P.L.L.C.



Nancy J. Leith  
Agent for Applicants  
Registration No. 45,309

SRL/NJL/ja  
Enclosures

465449\_1.DOC

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re application of:  KATO <i>et al.</i>  Appl. No.: <i>To Be Assigned</i> (U.S. National Phase of PCT/JP2004/005973)  I.A. Filed: May 6, 2004  For: <b>Freeze-Dried Preparation Containing Methylcobalamin and Process For Producing Same</b>	Confirmation No.: <i>To Be Assigned</i>  Art Unit: <i>To Be Assigned</i>  Examiner: <i>To Be Assigned</i>  Atty. Docket: 1089.0590000/SRL/NJL
--	---

**Information Disclosure Statement  
Filing Under 37 C.F.R. § 1.97(b)**

*Mail Stop PCT*

Commissioner for Patents  
PO Box 1450  
Alexandria, VA 22313-1450

Sir:

Listed on accompanying Forms PTO/SB/08A and PTO/SB/08B are documents that may be considered material to the examination of this application, in compliance with the duty of disclosure requirements of 37 C.F.R. §§ 1.56, 1.97 and 1.98. Copies of the documents are submitted herewith.

In accordance with 37 C.F.R. § 1.98(a)(3), Applicants' undersigned representative submits the following discussion of the relevance of the non-English language documents **FP1-FP8** cited on Form PTO/SB/08A:

Document **FP1**, JP 45-38059 B1, is in the Japanese language. An unverified English abstract of FP1 is cited as document **NPL7**.

Document **FP2**, JP 55-113721 A, is in the Japanese language. An unverified English abstract of FP2 is cited as document **NPL8**. In addition, document FP2 was

cited in a search report by a foreign patent office in the international application. A copy of the search report indicating the relevance of said document is submitted herewith.

Document **FP3**, JP 59-152327 A, is in the Japanese language. An unverified English abstract of FP3 is cited as document **NPL9**. In addition, document FP3 was cited in a search report by a foreign patent office in the international application. A copy of the search report indicating the relevance of said document is submitted herewith.

Document **FP4**, JP 62-38 A, is in the Japanese language. An unverified English abstract of FP4 is cited as document **NPL10**.

Document **FP5**, JP 63-3137 A, is in the Japanese language. An unverified English abstract of FP5 is cited as document **NPL11**.

Document **FP6**, JP 1-132514 A, is in the Japanese language. An unverified English abstract of FP6 is cited as document **NPL12**.

Document **FP7**, JP 9-136837 A, is in the Japanese language. An unverified English translation of FP7 is cited as document **NPL13**. In addition, document FP7 was cited in a search report by a foreign patent office in the international application. A copy of the search report indicating the relevance of said document is submitted herewith.

Document **FP8**, JP 10-218775 A, is in the Japanese language. An unverified English translation of FP8 is cited as document **NPL14**. In addition, document FP8 was cited in a search report by a foreign patent office in the international application. A copy of the search report indicating the relevance of said document is submitted herewith.

Where the publication date of a listed document does not provide a month of publication, the year of publication of the listed document is sufficiently earlier than the effective U.S. filing date and any foreign priority date so that the month of publication is not in issue. Applicants have listed publication dates on the attached IDS Forms based on information presently available to the undersigned. However, the listed publication dates should not be construed as an admission that the information was actually published on the date indicated.

Applicants reserve the right to establish the patentability of the claimed invention over any of the information provided herewith, and/or to prove that this information may not be prior art, and/or to prove that this information may not be enabling for the teachings purportedly offered.

This statement should not be construed as a representation that a search has been made, or that information more material to the examination of the present patent application does not exist. The Examiner is specifically requested not to rely solely on the material submitted herewith.

This Information Disclosure Statement is being filed within three months of the date of entry of the national stage as set forth in 37 C.F.R. § 1.491 in an international application. No statement or fee is required.

It is respectfully requested that the Examiner initial and return a copies of the enclosed IDS Forms, and indicate in the official file wrapper of this patent application that the documents have been considered.

The U.S. Patent and Trademark Office is hereby authorized to charge any fee deficiency, or credit any overpayment, to our Deposit Account No. 19-0036.

Respectfully submitted,

STERNE, KESSLER, GOLDSTEIN & FOX P.L.L.C.

*Nancy J. Leith*

Nancy J. Leith  
Agent for Applicants  
Registration No. 45,309

Date: November 15, 2005

1100 New York Avenue, N.W.  
Washington, D.C. 20005-3934  
(202) 371-2600

462137\_1.DOC

**Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB control number.**

Substitute for form 1449/PTO				<i>Complete if Known</i>	
<b>INFORMATION DISCLOSURE STATEMENT BY APPLICANT</b> <i>(Use as many sheets as necessary)</i>				Application Number	<i>To Be Assigned</i> (U.S. National Phase of PCT/JP2004/005973)
				I.A. Filing Date	May 6, 2004
				First Named Inventor	Akira KATO
				Art Unit	<i>To Be Assigned</i>
				Examiner Name	<i>To Be Assigned</i>
Sheet	1	of	1	Attorney Docket Number	1089.0590000/SRL/NJL

FOREIGN PATENT DOCUMENTS						
Examiner Initials*	Cite No. <sup>1</sup>	Foreign Patent Document	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear	T <sup>6</sup>
		Country Code <sup>3</sup> Number <sup>4</sup> Kind Code <sup>5</sup> (if known)				
/ZV/	FP1	JP 45-38059 B1	12/02/1970	Eisai Company Ltd.		
/ZV/	FP2	JP 55-113721 A	09/02/1980	Eisai Company Ltd.		
/ZV/	FP3	JP 59-152327 A	08/31/1984	Otsuka Pharmaceutical Company Ltd.		
/ZV/	FP4	JP 62-38 A	01/06/1987	Sankyo Company Ltd.		
/ZV/	FP5	JP 63-3137 A	01/08/1988	Matsushita Seiko Company Ltd.		
/ZV/	FP6	JP 1-132514 A	05/25/1989	Nippon Kayaku Company Ltd.		
/ZV/	FP7	JP 9-136837 A	05/27/1997	Merck Patent GmbH		
/ZV/	FP8	JP 10-218775 A	08/18/1998	Kaji Tatsuji		

462192\_1.DOC

Examiner Signature	/Zohreh Vakili/ (02/15/2008)	Date Considered	/Zohreh Vakili/ (02/15/2008)
--------------------	------------------------------	-----------------	------------------------------

\*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant. <sup>1</sup>Applicant's unique citation designation number (optional). <sup>2</sup>See Kinds Codes of USPTO Patent Documents at [www.uspto.gov](http://www.uspto.gov) or MPEP 901.04. <sup>3</sup>Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). <sup>4</sup>For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. <sup>5</sup>Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST.16 if possible. <sup>6</sup>Applicant is to place a check mark here if English language Translation is attached.

This collection of information is required by 37 CFR 1.97 and 1.98. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 2 hours to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

If you need assistance in completing the form, call 1-800-PTO-9199 (1-800-786-9199) and select option 2.

Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB control number.

Substitute for form 1449/PTO				<b>Complete if Known</b>	
				Application Number	To Be Assigned (U.S. National Phase of PCT/JP2004/005973)
				I.A Filing Date	May 6, 2004
				First Named Inventor	Akira KATO
				Art Unit	To Be Assigned
				Examiner Name	To Be Assigned
Sheet	1	of	2	Attorney Docket Number	1089.0590000/SRL/NJL

NON PATENT LITERATURE DOCUMENTS						
Examiner Initials*	Cite No. <sup>1</sup>	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume issue number(s), publisher, city and/or country where published				T <sup>2</sup>
/ZV/	NPL1	International Search Report for International Application No. PCT/JP2004/005973, Japanese Patent Office, mailed August 31, 2004				
/ZV/	NPL2	Izutsu, K.-i., et al., "Effects of sodium tetraborate and boric acid on nonisothermal mannitol crystallization in frozen solutions and freeze-dried solids," <i>Int. J. Pharm.</i> 273:85-93, Elsevier B.V. (April 2004)				
/ZV/	NPL3	Izutsu, K.-i., et al., "Decreased Protein-Stabilizing Effects of Cryoprotectants Due to Crystallization," <i>Pharm. Res.</i> 10:1232-1237, Plenum Publishing Corporation (1993)				
/ZV/	NPL4	Wu, S.-L., et al., "The formation and mechanism of multimerization in a freeze-dried peptide," <i>Int. J. Pharm.</i> 200:1-16, Elsevier Science B.V. (2000)				
/ZV/	NPL5	Pikal, M.J., et al., "The Effects of Formulation Variables on the Stability of Freeze-Dried Human Growth Hormone," <i>Pharm. Res.</i> 8:427-436, Plenum Publishing Corporation (1991)				
/ZV/	NPL6	Yoshinari, T., et al., "Crystallization of amorphous mannitol is retarded using boric acid," <i>Int. J. Pharm.</i> 258:109-120, Elsevier Science B.V. (June 2003)				
	NPL7	Dialog File 351, Accession No. 751840, Derwent WPI English abstract of JP 45-28050 B1, document EP1				
	NPL8	Patent Abstracts of Japan, unverified English abstract of JP 55-113721 A, document EP2				
	NPL9	Patent Abstracts of Japan, unverified English abstract of JP 59-152327 A, document EP3				
	NPL10	Patent Abstracts of Japan, unverified English abstract of JP 62-38 A, document EP4				

Examiner Signature	/Zohreh Vakili/ (02/15/2008)	Date Considered	/Zohreh Vakili/ (02/15/2008)
--------------------	------------------------------	-----------------	------------------------------

\*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

<sup>1</sup> Applicant's unique citation designation number (optional). <sup>2</sup> Applicant is to place a check mark here if English language Translation is attached.

This collection of information is required by 37 CFR 1.98. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 2 hours to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB control number.

Substitute for form 1449/PTO				<b>Complete if Known</b>	
				Application Number	To Be Assigned (U.S. National Phase of PCT/JP2004/005973)
				I.A Filing Date	May 6, 2004
				First Named Inventor	Akira KATO
				Art Unit	To Be Assigned
				Examiner Name	To Be Assigned
Sheet	2	of	2	Attorney Docket Number	1089.0590000/SRL/NJL

<b>NON PATENT LITERATURE DOCUMENTS</b>					
Examiner Initials*	Cite No. <sup>1</sup>	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume issue number(s), publisher, city and/or country where published			T <sup>2</sup>
NPL11		Patent Abstracts of Japan, unverified English abstract of JP 63-3137 A, document EP5			
NPL12		Patent Abstracts of Japan, unverified English abstract of JP 1-132514 A, document EP6			
NPL13		Patent Abstracts of Japan, unverified English translation of IP 9-136837 A, document EP7			
NPL14		Patent Abstracts of Japan, unverified English translation of JP 10-218775 A, document EP8			

462140\_1.DOC

ALL REFERENCES CONSIDERED EXCEPT WHERE LINED THROUGH. /ZV/ (06/21/2008)

Examiner Signature	/Zohreh Vakili/ (02/15/2008)	Date Considered	/Zohreh Vakili/ (02/15/2008)
--------------------	------------------------------	-----------------	------------------------------

\*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

<sup>1</sup> Applicant's unique citation designation number (optional). <sup>2</sup> Applicant is to place a check mark here if English language Translation is attached.

This collection of information is required by 37 CFR 1.98. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 2 hours to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.